

REMARKS

35 U.S.C. §112, 2d

Claims 39, 43, 47, 49, 51 and 59 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed and reconsideration is respectfully solicited.

In the Office Action, it was asserted that the use of the terms “excipient” and “binder” render certain claims indefinite because the identity or the identities of the excipient and binder have not been provided in the remainder of the claim.

Further to Applicant’s Request for Reconsideration, Applicant submits herewith a declaration of Donald J. Kerrish dated 6 October 2008 (Kerrish Declaration) for consideration in this rejection. As noted in the Kerrish Declaration at paragraph 6, the terms “excipient” and “binder” are understood and commonly used by those skilled in the art to which the application pertains. This declaration is additional evidence that the scope of the subject matter embraced by the claims is clear and would have been understood by those skilled in the art. Reconsideration and withdrawal of the rejection are respectfully solicited.

35 U.S.C. §103

Claims 39-53 and 59-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tam ‘097 in view of Liebowitz and further in view of Rudnic and Porter. The rejections are traversed and reconsideration is respectfully solicited.

Further to Applicant’s Request for Reconsideration, Applicant respectfully requests that the Kerrish Declaration be considered in the examination of Claims 39-53 and 59-63. As noted in paragraph 7 of the declaration, Ribavirin has been known since the 1970’s and has been characterized as a water-soluble compound existing in one of two polymorphic forms, which

have melting points of 166-168 °C and 174-176 °C, respectively. Ribavirin has been described as having poor processing characteristics, such as poor flow and low and variable tap density. Kerrish Decl. at ¶8, citing to U.S. Patent 5,914,128 to Liebowitz et al. at column 1, lines 15-29. Liebowitz et al. further described the undesirability of creating polymorphic forms of ribavirin which may occur during processes to produce ribavirin compositions. See U.S. Patent 5,914,128 at column 1, lines 30-35. Liebowitz reported that it was surprising to prepare a ribavirin composition substantially free of polymorphic forms by dry compaction. See Liebowitz at column 3, lines 40-50. The conventional wisdom at the time of the Liebowitz publication was that certain processing steps, including heat generated from a compaction step, would result in the formation of undesirable polymorphic forms of ribavirin. Kerrish Decl. at ¶8.

Given the discussion in Liebowitz and that ribavirin is a water-soluble compound, it was surprising that ribavirin compositions can be prepared by adding water to a ribavirin mixture without creating polymorphs, i.e., without causing the ribavirin in the mixture to convert from one polymorphic form to another polymorphic form. Kerrish Decl. at ¶9. Given the discussion in Liebowitz, it was further surprising that heating such a mixture did not create ribavirin polymorphs either. *Id.*

Applicant has provided evidence in the Kerrish Declaration that shows processes for preparing a ribavirin composition by adding water to a ribavirin mixture without creating polymorphs was surprising and that heating such a mixture without creating ribavirin polymorphs was further surprising. One of skill in the art would not have expected the results obtained by the claimed process. Accordingly, reconsideration of the rejection of claims 39-53 and 59-63 under 35 U.S.C. §103(a) in view of the declaration evidence and remarks made in Applicant's Request for Reconsideration are respectfully solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below. Accordingly, reconsideration and allowance of the application are respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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